

Amendment and Response

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Confirmation No.: 2357

Filed: 12 December 2003

For: VARIABLE VALVE APPARATUS AND METHODS

Remarks

The Final Office Action mailed 30 December 2005 has been received and reviewed. In this response (which is being filed with a Request for Continued Examination) claims 1 and 11 have been amended, claim 10 has been canceled, and new claims 23-30 are presented, leaving claims 1-9 & 11-30 pending after entry of this response. Reconsideration and withdrawal of the rejections are respectfully requested.

New Claims 23-30

New claims 23-30 are presented to provide Applicants with more comprehensive protection for the disclosed inventions. Support for new claims 23-30 can be found in the application as filed at, c.g., p. 6, line 1 to p. 7, line 9 as well as p. 9, line 31 to p. 10, line 24. Further support may also be found in, e.g., Figure 1. Entry and consideration of new claims 23-30 are respectfully requested.

The 35 U.S.C. §112, Second Paragraph, Rejection

Claims 1-22 were rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

Regarding the issues raised with respect to the phrase "a first major side" as found in the fourth line from the last in claim 1, Applicants have amended the phrase to recite "the first major side". As a result, Applicants respectfully submit that this issue is no longer present with respect to claim 1.

It was also asserted in the Office Action that, "[a]s to claims 1-22, the terms 'valved' and 'valve' are confusing, as the written specification and disclosure seems to describe a wall 64 in which an opening if (*sic*) formed by a laser, and not a valve." *Final Office Action*, p. 2. As further support for this rejection, it is also asserted that "[t]he relating of the term 'valve' with

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'piercing' (Paragraph 92) is a bit difficult to accept, as piercing does not seem to describe a valve. As a result, the Undersigned hesitates to accept that a piercing mechanism describes a valve." *Final Office Action*, pp. 4-5. Applicants respectfully submit that this reasoning is insufficient to support a rejection under § 112, second paragraph.

At the outset, Applicants note that the terms "valved" and "valve" are addressed in connection with this rejection as if the terms were recited alone in the claims. That is not, however, the case. In fact, the terms "valved" and "valve" are used to modify a noun. Claims 1-22 recite (in order of appearance) a "valved process chamber", "valve chamber", "valve septum", and "valve lip". In other words, the claims use "valve" or "valved" in the form of an adjective to describe a feature (e.g., process chamber, chamber, septum, or lip) that is a part of the fluid control structures. This distinction has not been addressed in the rejection and, Applicants submit, is another reason for reconsideration and withdrawal of this rejection.

In addition to failing to address the actual language of the rejected claims, the proper standard has not been applied. The proper standard to apply in assessing a claim under 35 U.S.C. § 112, second paragraph, is whether the claim as a whole "apprises one of ordinary skill in the art of its scope and, therefore, serves the notice function required by 35 U.S.C. 112, second paragraph, by providing clear warning to others as to what constitutes infringement of the patent." M.P.E.P. §2173.02, p. 2100-213 (8th Ed., Rev. 3, August 2005).

The reasoning presented as to why the use of the terms "valve" and "valved" in the claims does not meet the requirements of § 112, second paragraph is, essentially, that "valves are reusable" This assertion is coupled with the implication that a structure that cannot be both opened and closed cannot be a valve and, further, that the use of such a term in connection with a structure that cannot be both opened and closed.

Applicants respectfully disagree. As noted in Applicants' previous response, the art cited in the rejections under 35 U.S.C. §§ 102 & 103 (including U.S. Patent No. 6,063,589 to Kellogg et al. which is not commonly assigned) also uses the terms "valve" and "valved" to describe

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features that cannot be open and closed or reused. As a result, Applicants submit that the use of those terms would not render the claims indefinite to those of ordinary skill in the art.

For at least the above reasons, Applicants respectfully submit that claims 1-22 do meet the requirements of § 112, second paragraph. Reconsideration and withdrawal of the rejection of claims 1-22 are, therefore, respectfully requested.

The 35 U.S.C. §102 Rejection

Claims 1-3, 5, 8, 14, 16, 17, and 20 were rejected under 35 U.S.C. §102(b) as being anticipated by Godec et al. (U.S. Patent No. 5,976,468). This rejection is respectfully traversed.

In the interest of advancing prosecution, Applicants have amended claim 1 to incorporate the recitations of claim 10 – which was not subject to this anticipation rejection. As a result, this rejection has been rendered moot with respect to claims 1-3, 5, and 8.

With respect to method claims 14, 16, 17, and 20, Applicants submit that Godec et al. does not disclose, *inter alia*, either "detecting a characteristic of the sample material in the process chamber through the detection window" or "forming an opening in the valve septum at a selected location along the length of the process chamber, wherein the selected location is correlated to the detected characteristic of the sample material" as recited in claim 14 (from which claims 16, 17, and 20 depend).

These deficiencies were noted in Applicants' previous submission. In response, it is asserted in the Final Office Action "that vial 90 is a 'test tube' (col. 8, line 17, or Godec). Such vials are transparent, allowing a individual to determine if a sufficient material is in the vial before inserting the vial into the tester." *Final Office Action*, p. 5. Applicants note, however, that these assertions do not support a finding that Godec et al. teaches the steps recited in claim 14.

For example, there is no discussion as to how Godec et al. teaches that "the selected location is correlated to the detected characteristic of the sample material" as recited in claim 14.

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Rather, the needles 70 and 100 of Godec et al. will always pierce the membrane 94 at the same location and the openings in those needles will always be in the same location, regardless of any detected characteristic of material in the test tube 90.

If it is the intention of the Examiner to rely on inherency in support of the rejection of method claims 14, 16, 17, and 20, Applicants submit that the rejection fails to meet the requirements set for an anticipation rejection based on inherency, i.e., "[t]he fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic." *M.P.E.P.* § 2112, p. 2100-57, 8th Ed., Rev. 3, (August 2005) (emphasis in original) (citing *In re Rijckaert*, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993)). "In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original). No such basis has been provided to support this rejection.

In view of the above, Applicants respectfully request reconsideration and withdrawal of the anticipation rejection of claims 1-3, 5, 8, 14, 16, 17, and 20 in view of Godec et al.

The 35 U.S.C. §103 Rejections

Claim 21 was rejected under 35 U.S.C. §103(a) as being unpatentable over Godec et al. (U.S. Patent No. 5,976,468). This rejection is respectfully traversed.

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art references must teach or suggest all the claim limitations. See *M.P.E.P.* § 2143.

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Claim 21 depends from independent method claim 14. Applicants noted above with respect to the anticipation rejection of independent method claim 14 that Godec et al. does not teach, e.g., "detecting a characteristic of the sample material in the process chamber through the detection window." Nor does Godec et al. teach "forming an opening in the valve septum at a selected location along the length of the process chamber, wherein the selected location is correlated to the detected characteristic of the sample material." Further, the Office Action provides no assertions as to why or how one of ordinary skill in the art would modify the teachings of Godec et al. to include the missing elements as would be required for a *prima facie* case of obviousness.

For at least these reasons, Applicants submit that Godec et al. alone cannot support a case of *prima facie* case of obviousness with respect to claim 21. Reconsideration and withdrawal of this rejection are, therefore, respectfully requested.

Claims 1-18, 20, and 21 were rejected under 35 U.S.C. §103(a) as being unpatentable over Parthasarathy (U.S. Patent Publication No. 2003/0138779) in view of Kellogg et al (U.S. Patent No. 6,063,589). This rejection is respectfully traversed.

Applicants will address this rejection on the merits, but do expressly reserve the right to remove the Parthasarathy et al. reference from consideration as prior art in the future.

Again, to establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art references must teach or suggest all the claim limitations. See M.P.E.P. § 2143.

With respect to independent article claims 1 and 13 (and dependent claims 2-12), Applicants note that the Office Action does not identify any suggestion or motivation as to why

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or how one of ordinary skill in the art would modify the process chambers of Parthasarathy et al. to meet the recited limitation that the process chambers have a length greater than their width. In the absence of any discussion as to why or how one of ordinary skill in the art would modify the cited references to meet claims 1-13, a *prima facie* case of obviousness has not been established.

Applicants note that it was asserted in the Final Office Action that Applicants should "look at Figure 3 of Parthasarathy et al. Element 150a is three dimensional, and has a shape. The dimensions in the three dimensions are different." *Final Office Action*, p. 6.

Before doing so, however, it should be noted that the shape of the process chamber as recited in independent article claims 1 and 13 is defined "between opposing first and second major sides of the sample processing device, wherein the process chamber occupies a process chamber area on the sample processing device, and wherein the process chamber area comprises a length and a width transverse to the length, and further wherein the length is greater than the width."

Applicants have reviewed Figure 3 and note that it is an enlarged perspective view of circular process chamber 150a whose true shape (when viewed as defined in independent article claims 1 and 13) is seen in the plan view of Figure 2. Because process chamber 150a occupies a process chamber area that is circular, it cannot, by definition, have a length greater than its width as recited in claim 1.

For at least this reason, Applicants respectfully submit that a *prima facie* case of obviousness has not been established for article claims 1-13. Reconsideration and withdrawal of the rejection as applied to claims 1-13 are, therefore, respectfully requested.

Regarding method claims 14-18, 20 and 21, Applicants note that the shortcoming identified above with respect to independent article claim 1 applies equally to method claims 14-18, 20 and 21 (which recite the use of a process chamber with process chamber area having a length greater than its width).

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In addition, no discussion has been provided in support of the rejection of claims 14-18, 20 and 21 as to why or how one of ordinary skill in the art would modify and/or combine the methods of the cited references to reach the step of "forming an opening in the valve septum at a selected location along the length of the process chamber, wherein the selected location is correlated to the detected characteristic of the sample material." Although openings are formed in the structures of the cited references, no portion of either reference has been identified in the connection with this rejection to support an assertion that the references teach or suggest "forming an opening in the valve septum at a selected location along the length of the process chamber, wherein the selected location is correlated to the detected characteristic of the sample material."

For at least these reasons, Applicants respectfully submit that a *prima facie* case of obviousness has not been established for method claims 14-18, 20 and 21. Reconsideration and withdrawal of the rejection as applied to claims 14-18, 20, and 21 are, therefore, respectfully requested.

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Summary

It is respectfully submitted that pending claims 1-9 & 11-30 are in condition for allowance and notification to that effect is respectfully requested. The Examiner is invited to contact Applicants' Representatives, at the below-listed telephone number, if it is believed that prosecution of this application may be assisted thereby.

Respectfully submitted

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CERTIFICATE UNDER 37 CFR §1.8:

The undersigned hereby certifies that the Transmittal Letter and the paper(s), as described hereinabove, are being transmitted by facsimile in accordance with 37 CFR §1.6(d) to the Patent and Trademark Office, addressed to Mail Stop RCE, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 29th day of June, 2006, at 11:10 a.m. (Central Time).

By: R. GagliardiName: R. Gagliardi